



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 29, 2015

Novabay Pharmaceuticals, Inc.
Foresight Regulatory Strategies, Inc.
% Ms. Ellen M. Beucler
Vice President
187 Ballardvale Street, Suite 180
Wilmington, Massachusetts 01887

Re: K143351

Trade/Device Name: Icase Contact Lens Case

Regulation Number: 21 CFR 886.5928

Regulation Name: Soft (hydrophilic) Contact Lens Care Products

Regulatory Class: Class II

Product Code: LRX

Dated: March 30, 2015

Received: April 1, 2015

Dear Ms. Beucler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Kesia Y. Alexander -A

for Malvina B. Eydelman, MD
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K143351

Device Name

iCase Contact Lens Case

Indications for Use (*Describe*)

For storage of soft (hydrophilic), and rigid gas permeable (RGP) hard contact lenses during disinfection with buffered, saline, 3% hydrogen peroxide contact lens solution. Not to be used with multi-purpose (chemical) disinfection, heat disinfection or saline solutions.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary**NOVABAY PHARMACEUTICALS, INC.**
iCase Contact Lens Case**1. Applicant Information**

NovaBay Pharmaceuticals, Inc.
5980 Horton St., Suite 550
Emeryville, CA 94608

Contact Person: Dr. Charles Francavilla
Telephone No.: (510) 899 - 8831
Fax No.: (510) 280 - 8379
E-mail: cfrancavilla@novabaypharma.com
Date Prepared: April 28, 2015

2. Device Information

Classification name: Contact Lens Care Products
Device classification: Class II
Regulation number: 21 CFR 886.5928 (Soft (hydrophilic) contact lens care products)
Product code: LRX
Proprietary name: NovaBay Pharmaceuticals, Inc. iCase Contact Lens Case

3. Predicate Devices

NovaBay Pharmaceuticals, Inc. claims substantial equivalence to PMA No. P820040, AOSept Lens Care System (Reclassified to Class II in 1997), Trade Name “Clear Care Contact Lens Care System”, CIBA Vision.

4. Description of Device

The iCase is a personal contact lens case used with one step hydrogen peroxide (H_2O_2) lens disinfecting/cleaning solutions. The iCase monitors the initial rate of neutralization of hydrogen peroxide (H_2O_2) and indicates the status of the disinfection cycle using the LED display in the cap. The iCase LED display and monitoring system are disabled after 65 cycles of use to promote routine lens case replacement.

5. Indications for Use

The NovaBay Pharmaceuticals, Inc. iCase contact lens case is indicated for the storage of soft (hydrophilic), and rigid gas permeable (RGP) hard contact lenses during disinfection with buffered, saline, 3% hydrogen peroxide contact lens solution. Not to be used with multi-purpose (chemical) disinfection, heat disinfection or saline solutions.

6. Performance Data

The key components of any hydrogen peroxide disinfection case includes: plastic vial, lens baskets, vented screw cap and catalytic platinum disk. The iCase Contact Lens Case and the predicate device incorporate all of these same components with identical functions.

The key electrical components of the iCase includes: power supply (battery), sensors, microcontroller and light emitting diodes. These components are unique to the iCase Contact Lens Case. The iCase Contact Lens Case with the integrated electrical components and software has undergone extensive evaluation and testing for IEC electrical safety testing, Risk Analysis, Device Hazard Analysis, Corrosion testing, Software validation and Cycling studies including peroxide degradation measurements.

Non-Clinical Data

The iCase Contact Lens Case was evaluated for Biocompatibility safety in accordance with the following standards. The iCase component testing included Cytotoxicity, Systemic Toxicity and Primary Ocular Irritation. The test results indicate the components are safe for the intended use.

- ISO Part 10993 Biological Evaluation of Medical Devices.

Electrical Safety Data

The iCase Contact Lens Case was evaluated for electrical safety in accordance with the following standards.

- IEC 60601- 1 Medical Electrical Equipment Part 1: General Requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General Requirements for safety – Collateral Standard: Usability – Application of Usability to Medical Devices.

- IEC 60601-1-11 Medical Electrical Equipment Part 1-11: General Requirements for basic safety and essential performance, Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems use in the Home Healthcare Environment,
- IEC 62366 Medical Devices - Application of Usability Engineering to Medical Devices.

The iCase Contact Lens Case complies with the applicable sections of the referenced electrical standards. The iCase red/yellow indicator lights vary from the standard, as they do not indicate Warning/Caution as listed 60601-1 Section 7.8.1.

The iCase Contact Lens Case utilizes data acquisition software to monitor the status of the peroxide neutralization process. The iCase software has been evaluated in accordance with FDA guidance, General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002 and the FDA Guidance for Premarket Submissions for Software Contained in Medical Devices, May 2005. The iCase Contact Lens Case complies with the applicable sections of the referenced software validation guidance.

Clinical Data

Clinical studies involving contact lens wear were unnecessary for this application. Lens care hydrogen peroxide solutions used with this iCase Contact Lens Case are already cleared for use as cleaning, rinsing, disinfection and storage solutions for contact lenses.

Conclusion

Based upon the test data presented, the NovaBay Pharmaceuticals, Inc. iCase Contact Lens Case is as safe, as effective and performs as well as the predicate device. A comparison of the new device and the predicate device is presented in Table 1.

7. Substantial Equivalence

The claim of substantial equivalence to the approved PMA No. P820040, AOSept Lens Care System (Reclassified to Class II in 1997), Trade Name “Clear Care Contact Lens Care System, is supported by the Comparison of Characteristics in Table 1. The predicate device was approved under the FDA product code LPN (accessories, soft lens products) and included a lens care solution and lens case. The iCase 510(k) application includes only a lens case and is identified by the FDA product code LRX (case, contact lens).

The iCase Contact Lens Case and the Clear Care contact lens case are similar in design and volume. Both lens cases are manufactured from similar materials that have been proven to be safe for use. Both lens cases can be used for one step hydrogen peroxide disinfection treatments. The new components used in the iCase Contact Lens Case have been evaluated for electrical safety and validated for their intended functions and do not pose any new risks for safety and effectiveness. Therefore, NovaBay Pharmaceuticals, Inc. iCase Contact Lens Case is substantially equivalent to the predicate device.

Table 1 Comparison of Characteristics

	NovaBay Pharmaceuticals, Inc. iCase	Clear Care CIBA VISION
Device Name	Contact Lens Case	Contact Lens Case
Trade Name	iCase Contact Lens Case	Clear Care Contact Lens Case
Document Number	510(k) K143351	PMA No. P820040
Classification	Ophthalmic	Ophthalmic
Product Code	LRX	LPN
Regulation Number	21 CFR 886.5928	21 CFR 886.5928
Class	II	II
Intended Use	For use during 3% hydrogen peroxide cleaning, disinfection and storage of soft (hydrophilic) and rigid gas permeable contact lenses.	For use during 3% hydrogen peroxide cleaning, disinfection and storage of soft (hydrophilic) and rigid gas permeable contact lenses.
Disinfection Type	3% Hydrogen Peroxide catalyzed by platinum coated disk	3% Hydrogen Peroxide catalyzed by platinum coated disk
Disinfection Cycle	Minimum of 6 hours	Minimum of 6 hours
Vial Design	Barrel style vented lens case with plastic screw top. Lens baskets and a neutralizing platinum disk are suspended from the cap	Barrel style vented lens case with plastic screw top. Lens baskets and a neutralizing platinum disk are suspended from the cap
Power Supply	3 V coin style battery hermetically sealed in the vial cap supplies power to internal clock and sensors	None
Cycle Indicator Lights	The screw cap contains three colored LED lights that indicate the status of the neutralization cycle	None
Cycle Timer	An internal timer monitors the length of the 6 hour neutralization cycle	Patients use an external timer to monitor the 6 hour neutralization cycle
Materials	Plastic resin vial, lens baskets and screw cap with a platinum coated neutralizing disk	Plastic resin vial, lens baskets and screw cap with a platinum coated neutralizing disk
Biocompatibility	Components used in this lens case have been evaluated in accordance with Part 10993 of the ISO standard for Biological Evaluation. Test results indicate the test article meets the ISO standards	Components used in this lens case have been evaluated in accordance with FDA Guidance for lens case materials.